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Certified Mail

July 23, 2002

Document Processing Desk [6(a)(2)]
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Crystal Mall 2 - Room 266A
1921 Jefferson Davis Highway
Arlington, VA 22202
Attention: Kathryn Bouve

Dear Ms. Bouve:

**SUBJECT: SUBMISSION OF INDEPENDENT REVIEW OF
EPIDEMIOLOGY DATA FOR ATRAZINE
TRIAZINES SPECIAL REVIEW DOCKET (OPP-30000-60)**

In accordance with an agreement with the Agency regarding the enclosed report, Syngenta Crop Protection, Inc. is providing information on atrazine consistent with the Agency's current interpretation of FIFRA Section 6(a)(2) reporting requirements as it relates to potential adverse effects. Enclosed please find three copies each of a transmittal document and a single data volume that contains an independent evaluation of a previously submitted follow-up epidemiological cancer incidence study of workers at the Syngenta St. Gabriel, LA manufacturing facility.

There have been a series of six epidemiological studies of workers at our manufacturing facilities provided to the EPA since 1993. The most recent was provided to the Agency on October 12, 2001 (Delzell, et al, 2001; *A Follow-up Study of Cancer Incidence Among Workers in Triazine Operations at the Novartis St. Gabriel Plant. EPA MRID NO. 45518401*).

On May 22, 2002 Mark Hartman provided Janis McFarland a copy of a March 25, 2002 EPA review of this and an earlier epidemiological report from Delzell, et al. Syngenta appreciated getting a copy of the review and also appreciates the time and efforts of Dr. Blondell and the external reviewers.

In February 2002, as one part of Syngenta's ongoing worker wellness program, we had asked Dr. Jack Mandel (Vice President of Health and Environmental Groups, Exponent, Inc) to convene a separate panel of epidemiologists to review Dr. Delzell's most recent report noted above.

The panel provided specific focus on understanding the impact of screening associated with prostate-specific antigen testing. The panel was convened in early March and in addition to Dr. Jack Mandel was comprised of the following epidemiologists

- **Hans-Olov Adami, M.D., Ph.D.** - Professor and Chairman, Department of Medical Epidemiology, Karolinska Institutet
- **Graham Colditz, M.D., Dr.P.H.** - Professor, Department of Epidemiology, School of Public Health, Harvard University
- **Dimitrios Trichopoulos, M.D.** - Professor of Epidemiology and Vincent L. Gregory Professor of Cancer Epidemiology, Department of Epidemiology, School of Public Health, Harvard University

On July 3, 2002 we received an unsigned/unformatted report from the independent panel titled:

"An Evaluation of the Report by Dr. Delzell et al. on A follow-up study of cancer incidence among workers in triazine operations at the Novartis St. Gabriel plant"

The report included a comprehensive analysis of the impact of PSA screening and reached conclusions similar to those reached by Dr. Delzell, et al., and also in the EPA review. This report was provided in an electronic mail message to you and various other Agency staff on July 9, 2002. The enclosed submission formally provides the signed and formatted copy of the report to the EPA.

The panel report confirms that extensive PSA testing detects prostate cancer at an earlier age and thereby increases the incidence to levels higher than in populations with a lower frequency of PSA testing. The conclusion of the attached panel report is as follows:

"Following the introduction of systematic widespread PSA testing in the Novartis St. Gabriel Plant, prostate cancer incidence has increased as much as, but no more than would have been expected on the basis of empirical evidence and biological considerations concerning the consequences of PSA screening on reported prostate cancer incidence. There is neither a need to invoke, nor

evidence to support, the contribution of environmental factors in the particular occupational setting on prostate carcinogenesis."

If there are any questions or request for further clarification regarding this or any related topics, please feel free to contact either Janis McFarland at (336) 632-2354 or me at (336) 632-7207. We will continue to keep you informed of ongoing work in this area.

Sincerely,

A handwritten signature in black ink, appearing to read "Thomas J. Parshley". The signature is fluid and cursive, with the first name "Thomas" and last name "Parshley" clearly distinguishable.

Thomas J. Parshley
Senior Regulatory Product Manager
Regulatory Affairs

CC: Kimberly Lowe (EPA/SRRD)